

## REMARKS

In the Office Action issued on November 12, 2008, the Examiner:

- rejected claims 1, 2 and 8 under 35 U.S.C. §102(b) as being anticipated by Shaknovich (United States Patent No. 5,807,398);
- rejected claims 4 and 11 under 35 U.S.C. §103(a) as being unpatentably obvious over Shaknovich in view of Kirkman (United States Patent No. 6,071,263);
- rejected claim 12 under 35 U.S.C. §103(a) as being unpatentably obvious over Shaknovich in view of Pavcnik (United States Published Application No. 20010039450);
- rejected claims 13 and 14 under 35 U.S.C. §103(a) as being unpatentably obvious over Shaknovich in view of Levine (United States Published Application No. 20040087965);
- rejected claim 18 under 35 U.S.C. §103(a) as being unpatentably obvious over Shaknovich in view of Levine and further in view of Pavcnik.

The Applicants have fully considered the Office Action and cited references and submit this Reply and Amendment in response to the Examiner's rejections. Reconsideration of the application for patent is requested.

Preliminary matter – Summary of Interview conducted on November 20, 2008

The undersigned attorney thanks the Examiner for the telephone interview

held on November 20, 2008. In the interview, the amendments made herein to independent Claim 1 were discussed in comparison to Shaknovich. Figures 5 and 6 of the current application were discussed as examples of the claimed method, *in which the deploying step is conducted while the spacing step is being performed.*

Figures 2 and 5 of Shaknovich were specifically discussed in contrast to the amendments made to Claim 1 to illustrate the *contrast between the separate spacing and deploying steps of Shaknovich and the concurrent performance of the spacing and deploying steps that is required by the amendments made herein.*

The Examiner expressed her belief that these amendments overcome the prior art of record. The Applicants appreciate the Examiner's time and helpful discussion on the issue.

#### Preliminary matter – Cancellation of claims 13, 14, and 18 not recognized

The Applicants cancelled claims 13, 14, and 18 in the Reply and Amendment filed on July 2, 2008 in response to the Office action issued on June 18, 2008. The action issued on November 12, 2008, nevertheless, recites rejections of these claims.

The Applicants respectfully request that the Examiner recognize the cancellation of these claims in the next Office Action.

#### Amendments to the Claims

**Applicants have herein amended independent claim 1 to require**

**that “the deploying step is performed while the spacing step is being performed.”**

This amendment to the claims is fully supported by the application as filed; no new matter has been introduced. Exemplary support is found in Figures 5 and 6 and the accompanying discussion.

For example, paragraph [0041] indicates that:

“[o]nce the basket 64 reaches the distal end 14 of the elongate member 12, the basket 64 is advanced out of the distal end 14. This causes the basket 64 to take its enlarged configuration, as illustrated in FIG. 5”

Paragraph [0042] indicates that:

“[a]s a result of the enlargement of the basket 64, the elongate member 12 is spaced from an interior wall surface 54 of the body vessel 50 by a distance 80.”

Finally, paragraph [0043] describes the performance of the deploying step:

“FIG. 6 illustrates the deployment of an expandable intraluminal medical device 22 according to the new method. In FIG. 6, the sheath 24 has been retracted and the expandable intraluminal medical device 22 has, as a result, been deployed. Because of the spacing of the elongate member 12 from the wall surface 54 provided by the basket 64, a functional mechanism 82 of the expandable intraluminal device 22 is spaced from an interior wall surface 54 of the vessel 50 by a distance 84. In FIG. 6, the expandable intraluminal device 22 comprises a prosthetic venous valve, and the functional mechanism 82 comprises the valve mechanism of the prosthetic valve 22. The spacing provided by the basket 64 positions the valve mechanism 80 near the geometric center of the vessel 50, which is expected to provide good function of the prosthetic valve 22.”

Additional exemplary support for the amendment to claim 1 is found in paragraph [0039], which describes the use of a basket as the means for spacing a portion of the elongate member from an interior wall surface of the body vessel.

Paragraph [0039] provides, in pertinent part:

"Baskets have not been used, however, to space elongate members from vessel walls during deployment of an expandable intraluminal device from the elongate member."

**The Applicants have made the amendments to claim 1 in response to the Examiner's stated concerns regarding the prior amendments to the claim, which were made in good faith to distinguish the cited references on the same point. As such, the Applicants respectfully submit that the amendments presented herein can properly be entered under the provisions of 37 C.F.R. §1.116 to place the claims in better condition for appeal, should the Applicants decide to pursue an appeal.**

Rejection of Claims 1, 2 and 8 under 35 U.S.C. §102

The Examiner rejected Claims 1, 2 and 8 under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 5,807,398 to Shaknovich ("Shaknovich"). Specifically, the Examiner indicated that Shaknovich "discloses a method for delivering and deploying an expandable intraluminal device" that includes the steps recited in Claims 1, 2 and 8 of the present application for patent.

Shaknovich teaches a delivery system that is suitable for use in "pre-dilatation," a technique used in some stent deployments to pre-dilate an occluded portion of a vessel prior to deployment of the stent at the occlusion.

**As amended herein and described above, independent claim 1, from which all remaining claims depend, explicitly requires that the step of deploying the expandable intraluminal medical device be conducted *while* the step of spacing a portion of the elongate member from a wall surface of the body vessel is being performed.**

Thorough review of Shaknovich reveals a complete absence of any teaching of a deploying step that is performed while a spacing step meeting the limitations of the spacing step of claim 1 is being performed. As such, the reference does not anticipate Claim 1 or any of the related dependent claims. The Applicants respectfully request withdrawal of this rejection of the claims.

#### Rejection of Claims 4 and 11 under 35 U.S.C. §103

The Examiner rejected Claims 4 and 11 under 35 U.S.C. §103(a) as being unpatentably obvious over Shaknovich in view of United States Patent No. 5,807,398 to Kirkman ("Kirkman"). Specifically, the Examiner indicated that Shaknovich "discloses the claimed invention except for the means for spacing comprising a basket formed from four wires having expanded and collapsed configurations and the step of activating the means for spacing includes retracting the sheath from a position about the means for spacing."

Both claims 4 and 11 depend from Claim 1 and, therefore, include all limitations of that claim. As described above, Claim 1 has been amended herein to require that the deploying step be performed while the spacing step is being performed. Also as described above, Shaknovich does not teach or suggest such a performance of deploying and spacing steps. Kirkman fails to cure this defect of Shaknovich and, as such, the rejection does not present a *prima facie* case of obviousness because it fails to teach or suggest each and every limitation of the rejected claims.

Applicants respectfully request reconsideration and withdrawal of the rejection of Claims 4 and 11 in light of the amendments made herein.

#### Rejection of Claim 12 under 35 U.S.C. §103

The Examiner rejected Claim 12 under 35 U.S.C. §103(a) as being unpatentably obvious over Shaknovich in view of United States Published Application No. 20010039450 to Pavcnik ("Pavcnik"). Specifically, the Examiner indicated that Shaknovich "discloses the claimed steps except for the expandable intraluminal medical device comprising a venous valve."

Claim 12 depends from Claim 1 and, therefore, includes all limitations of that claim. As described above, Claim 1 has been amended herein to require that the deploying step be performed while the spacing step is being performed. Also as described above, Shaknovich does not teach or suggest such a performance of deploying and spacing steps. Pavcnik fails to cure this defect of Shaknovich and, as such, the rejection does not present a *prima facie* case of obviousness because it fails to teach or suggest each and every limitation of the rejected claims.

Applicants respectfully request reconsideration and withdrawal of the rejection of Claim 12 in light of the amendments made herein.

#### Rejection of Claims 13 and 14 under 35 U.S.C. §103

As indicated above, the Applicants have previously cancelled claims 13 and 14. The rejection of these claims is, therefore, moot.

The Applicants respectfully request that the Examiner recognize the cancellation of these claims by withdrawing the rejection in the next Office Action.

#### Rejection of Claim 18 under 35 U.S.C. §103

As indicated above, the Applicants have previously cancelled claim 18. The

rejection of this claim is, therefore, moot.

The Applicants respectfully request that the Examiner recognize the cancellation of this claim by withdrawing the rejection in the next Office Action.

## **CONCLUSION**

The Applicants have fully responded to the rejections listed by the Examiner in the November 12, 2008 Office Action. The Applicants have submitted this Reply and Amendment under the provisions of 37 C.F.R. §1.116 in order to present the claims in better condition for appeal, should an appeal be pursued. Entry of the amendment under the provisions of §1.116 is respectfully requested. Additionally, Applicants respectfully request that the Examiner issue an Advisory Action indicating the status of this Reply and Amendment.

The Applicants maintain that a Notice of Allowability relating to all claims currently under consideration is appropriate and respectfully request that the Examiner issue such Notice upon entry of this Reply and Amendment.

Should the Examiner have any questions regarding this Reply and Amendment, or the remarks contained herein, the undersigned attorney would welcome the opportunity to discuss such matters with the Examiner.

Respectfully submitted,

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